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One-year economic evaluation of intensive *vs* conventional patient education and supervision for self-management of new asthmatic patients

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The purpose was to compare the short-term cost-effectiveness of intensive *vs* conventional education and supervision for the self-management of mild asthmatic patients. Consecutive newly diagnosed asthmatic patients ($n=162$) were randomized into an intervention group (IG) and a control group (CG) with 1 yr of treatment and follow-up. Intensive education was given to 77 patients at visits every third month in the outpatient clinic. Eighty CG patients received conventional education and advice at the baseline visit only. All patients received similar inhaled anti-inflammatory treatment.

At baseline and at 12 months standard clinical lung functions and health-related quality of life (HRQOL) were measured, the latter by the disease-specific St George's Respiratory Questionnaire and the generic 15D. Furthermore, the use of extra health care services, medication and sickness days were recorded. The IG experienced a significant improvement in all clinical and HRQOL outcome variables. The same applied to the CG except spirometric values. The groups differed significantly only in terms of FEV_1 ($P<0{\cdot}05$) in favour of the IG. There was a significant difference between the groups in extra costs. The mean cost was FIM 2351 per patient (£294 sterling) in the CG and FIM 2757 per patient (£345) in the IG, of which the intervention cost was FIM 1978 per patient (£247). In 1 yr follow-up the intensive education programme did not prove to be cost effective but was dominated by the conventional one regardless of what effectiveness measure was used. Also, a purely monetary cost–benefit calculation showed that the intervention resulted in a negative net benefit (loss) of FIM 406 per patient (£51). A longer follow-up may be needed before definitive conclusions about the cost-effectiveness of this kind of intervention can be drawn.

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Introduction

The total social costs of asthma are rising in Finland as the number of asthmatic patients increases. Most patients in Finland (60%) have a mild form of the disease and account for approximately 20% of total social costs, mainly as direct costs. About 60% of total costs are attributed to those suffering from severe or moderate asthma, the most significant costs being indirect ones. For better treatment results in the long run, and consequently fewer severe asthma cases and thus decreased social costs, patients today are encouraged from the onset to assume an active responsibility for managing their disease. Therefore they should be familiar with the principles of treatment and be guided in self-management (1).

Patient education and self-management have been reported to decrease asthma morbidity (2–7) or to be cost effective in many studies among chronic, mostly moderate or severe asthmatics (8–14). However, these evaluations have been based on selected outcomes and costs, some studies have been uncontrolled or the treatment was based on special trial medication.

The aim of this study was to compare an intensive patient education and supervision programme for self-management *vs* a conventional approach among newly diagnosed asthmatic patients in terms of cost–benefit and cost-effectiveness. The study was based on a randomized clinical trial with treatment based on usual clinical practice in both groups. Evaluation was made after the first treatment year. All customary clinical outcome measurements were used with health-related quality-of-life (HRQOL) instruments.

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TABLE 1. Baseline characteristics of the patients (standard deviations in parentheses)

	Intervention (n=80)	Control (n=82)
Sex (m, f)	25, 55	35, 47
Mean age (years) (range)	43·1 (18–76)	44·2 (19–76)
Atopy*	52	39
Current smokers	19	16
Forced vital capacity (FVC) (% of predicted)	95·1 (12·5)	92·5 (14·8)
Forced expiratory volume in one second (FEV_1) (% of predicted)	86·1 (14·0)	82·8 (14·8)
FEV_1/FVC	90·0 (10·0)	89·1 (9·7)
Peak expiratory flow (PEF) (% of predicted)	84·3 (11·4)	83·4 (13·5)
15D score	0·89 (0·10)	0·89 (0·10)
SGRQ total score	27·0 (14·6)	27·7 (15·6)
Treatment:		
Inhaled corticosteroid	75	77
Nedocromil	5	5

*At least one positive skin prick test reaction to common allergens.

Both extra direct and indirect costs were calculated for economic analysis.

Methods

PATIENTS

Between September 1991 and February 1993, 162 consecutive new asthmatic patients were diagnosed according to the criteria of the American Thoracic Society (15) in South Karelia Central Hospital. They all showed a reversible airways obstruction with an increase of at least 15% in the forced expiratory volume in 1 s (FEV_1) or in peak expiratory flow (PEF) in response to bronchodilators. The patients had not previously used inhaled anti-inflammatory asthma medication.

At the time of diagnosis, the patients were informed about the study. One month later, they visited the attending chest physician for conventional guidance in treatment and self-management. After that, they were randomized by using a computerized list with consecutive numbers. The nurse on duty then made the next appointments according to the study plan.

The intervention group (IG) consisted of 80 patients and the control group (CG) of 82 patients. Patient characteristics at baseline are given in Table 1.

The routine treatment programme was followed. The principle is to use higher doses of inhaled corticosteroid or nedocromil during the first 2 months and then to decrease doses according to PEF measures. Most patients had inhaled corticosteroid from the beginning. Ten patients started with nedocromil. The medication was prescribed for 1 yr at the randomization visit. The pharmacies delivered the drugs for 3 months use at a time. The prescribed mean maintenance doses were 1·01 mg beclomethasone (Bcl), 0·97 mg budesonide (B) and 11 mg nedocromil (N) in the IG and 1·03 mg Bcl, 0·97 mg B and 10 mg N in the CG. Inhaled bronchodilating medication was used according to need. Corticosteroid tablets were not prescribed in advance during the first year of treatment. The compliance was checked at 1 yr on the basis of oral information given by the patient.

The study plan was approved by the Hospital Ethical Committee and the informed consent was obtained from all patients.

THE EDUCATION PROGRAMME

The conventional patient education programme commenced at the visit for diagnosis and consisted of basic education for the use of inhaled drugs, peak expiratory flow (PEF) follow-up and the principles of treatment. The programme was administered by two qualified respiratory nurses specially trained for that purpose. At the randomization visit the patient was educated in guided self-management and a videotape concerning asthma was shown to both groups.

The education continued in the IG at the visits to the clinic every third month and was given alternately by the nurse or attending chest physician. The time used for each visit was 30 min. The visit to the chest physician after 6 months was for supervising education and treatment, but no changes were made in medication at this visit. The first visit, after 3 months of treatment, was conducted by the same nurse who began the education. The self-management plan, use of drugs and PEF follow-ups were checked, misuse habits were corrected and treatment principles repeated. Between 6 and 9 months all patients participated in a 2 h education programme, given by a qualified physiotherapist and two qualified nurses, one of whom specialized in social affairs and the other in rehabilitation. The course was attended by two or three patients at a time.

The CG received conventional education at baseline only. They were advised to adjust their medication according to the self-management plan and to contact their health centre whenever they had symptoms or other problems. Their next planned visit was 11 months after randomization.

SELF-MANAGEMENT PLAN

A peak-flow meter and a diary were given to both groups for the first year. Patients were asked to follow their PEF values whenever symptoms appeared and at least for 2 weeks every third month, recording the values in the diary. This plan is approximately the same as the one later stated in the Finnish asthma programme (1).

TABLE 2. The mean values of lung functions (as a percentage from predicted) at baseline and at 1 yr follow-up in the intervention and control groups (95% CI in parentheses)

	Intervention group		Control group		Difference between the groups at 1 yr, *P* values
	At baseline	At 1 yr	At baseline	At 1 yr	
FVC	94·7 (91·8–97·6)	99·8*** (96·6–102·9)	92·5 (89·2–95·6)	94·7 (91·3– 98·1)	0·08
FEV_1	85·7 (82·5–88·9)	92·3*** (88·5–96·1)	82·8 (79·5–86·1)	84·7 (81·0– 88·4)	0·02
FEV%	90·0 (87·8–92·2)	91·9* (89·7–94·2)	89·1 (86·9–91·2)	88·9 (86·6– 91·2)	0·18
PEF	84·2 (81·6–86·7)	91·6*** (88·7–94·4)	83·4 (80·4–86·4)	87·1** (83·8– 90·5)	0·17
PD_{15} (mg ml^{-1}) geometric mean	0·10 (0·08–0·13)	0·31*** (0·24–0·41)	0·10 (0·08–0·13)	0·25 (0·18–0·34)	0·56
As dose steps	0·54 (0·36–0·72)	1·41*** (1·19–1·63)	0·58 (0·40–0·76)	1·23*** (1·00– 1·47)	0·28

Significance of the difference between baseline and one year, paired samples *t* test: ***$P<0·001$ **$P<0·01$ *$P<0·05$.
FVC, forced vital capacity; FEV_1, forced expiratory volume in 1 s; PD_{15}, airway responsiveness, provocative dose mg of histamine.

The plan was written in the diary as follows:

- If the PEF value falls below 80–85% of the predicted or of the individual's optimal value, the inhaled corticosteroid or nedocromil dosage should be doubled until the PEF level is normal and stabilized.
- If the PEF value falls below 70%, double the dosage and contact your doctor.
- If the PEF value falls below 50%, go to the emergency department.
- Use your inhaled bronchodilating drug whenever you have symptoms.

Both groups recorded the use of extra health care services, extra medication and sickness days in the diary.

OUTCOME MEASUREMENTS

Clinical measurements at baseline and at 12 months were performed at least 12 h after the last use of bronchodilating drugs. A flow volume spirometer, Medikro 101 (Medikro Ltd, Kuopio, Finland) calibrated daily according to standard quality criteria, was used for measuring forced vital capacity (FVC) and forced expiratory volume in 1 s (FEV_1). $FEV_1/FVC=FEV\%$ was then calculated. PEF was measured by Wright's peak-flow meter during the visit to the clinic. The Finnish normal spirometric (16) and Nunn's PEF (17) values were used and adjusted for age, gender and height. The results are given as a percentage from normal values (Table 2). Airway responsiveness was measured by the provocative dose of histamine required to cause a 15% fall in FEV_1 (PD_{15}) (18). The results are also expressed as dose steps, e.g. step 0 is PD_{15} <0·11 mg; step 1 is PD_{15}=0·11–0·4 mg, step 2 is PD_{15}=0·41–1·6 mg and step 3 is PD_{15} >1·6 mg. Changes in airway responsiveness were expressed as the geometric mean mg/ml of histamine and as the mean change in dose steps of PD_{15} (Table 2).

HRQOL MEASUREMENTS

The 15D is a generic HRQOL instrument with 15 dimensions: moving, seeing, hearing, breathing, sleeping, eating, communicating, eliminating, working, social participation, mental functioning, pain–ache, depression, distress and perceived health. Each dimension is divided into four or five ordinal levels. Individuals choose from each dimension the level that best describes his or her health status at that moment. The instrument also includes a system of preference weights, elicited in a population survey, by which the responses to the dimensions are converted into a single-index score (15D score) on a 0–1 scale (1 is full HRQOL, 0 being death) (19,20). Among the Finnish population the average 15D score in age group 35–44 years is 0·95 and in age group 65–75 years 0·86 (21). The 15D can be used both as a single-index number measure and as a profile measure.

The St George's Respiratory Questionnaire (SGRQ) measures the experience of well-being and the impairment of quality of life caused by a respiratory disease and is thus disease specific. Seventy-six items are divided into three domains – symptoms, activity and impact on daily life – from which the total score is calculated (22–24). Zero represents the best possible health situation and 100 the

worst. The patients completed the questionnaires in hospital during their visits.

COSTS

Costs are based on the actual cost in South Karelia Central Hospital in 1993. The cost of a visit to the lung clinic was FIM 773 including the lung function measurements (£1 sterling=approx. FIM 8), that of an inpatient day FIM 1200 and the cost of a visit to the emergency clinic FIM 1200. These prices include all cost items (labour, capital, maintenance etc.) and the average secretarial work needed for each visit. Visits to public health centres were valued at the mean cost of such visits in Finland (FIM 178). Any extra drugs used (oral corticosteroids and antibiotics) were valued at average retail prices. The educating nurse used on average 1·5 h per patient for education and arranging appointments. The time used by the nurses and physiotherapist was valued at their gross salary including social security contributions, FIM 100 h^{-1}. The average return transportation cost of a central hospital visit was FIM 48 and that of a health centre visit FIM 24.

All sickness days, the time required for intervention visits including time used for travelling and the average time spent on extra health care visits were recorded for the calculation of indirect costs. The total working time thus lost was valued at the average daily gross wage rate in Finland, including social security contributions (FIM 711 day^{-1}). The cost of diagnosis, the visit for randomization and the follow-up visit at 12 months were not included, since they were the same in both groups and do not thus affect the relative costs of the alternatives.

A cost-effectiveness ratio was calculated for both alternatives with effectiveness measured by all outcome variables. Similarly incremental cost-effectiveness ratios were derived for the intervention with the conventional programme as the comparator. The net monetary benefit from the intervention was calculated by subtracting from the intervention cost the saving due to the intervention (cost of conventional programme minus the extra costs in the intervention programme).

STATISTICAL ANALYSIS

Apart from airway responsiveness, all other outcome variables are reported as mean values with a 95% confidence interval. Because of a skewed distribution, geometric mean was calculated for airway responsiveness. Differences between the groups in all variables at baseline and at 1 yr were tested by using one-way analysis of variance (ANOVA). Differences in outcome variables between baseline and 1 yr follow-up within the groups were tested by using a paired t-test. A P-value <0·05 was considered significant. Because of skewed distributions, Mann–Whitney U tests were used to compare the differences in costs between the groups. The statistical significance of differences in cost-effectiveness ratios between the groups was not analysed owing to a lack of an applicable test (such as the t test).

Results

The randomization was successful since there was no significant difference between the groups at baseline in any variable. Three patients from the IG dropped out, because they did not show up for follow-up visits. In the control group one patient died in a traffic accident and another had moved.

Airway responsiveness was tested for 78 patients at baseline in the IG. Two were not tested: one was pregnant and the other had a common cold during the last 5 weeks. In the CG, 72 patients were tested. Ten patients were not tested: one was pregnant, seven had a common cold and two had acute obstructions.

All clinical and other outcome variables indicated a significant improvement in the IG during the treatment (P<0·001 except in FEV% P<0·05). Apart from no significant change in lung function variables, the results were similar in the CG. At 1 yr the IG showed a better result in all outcome variables, but statistically the groups differed significantly from each other only in FEV_1 (Tables 2 and 3).

The information given by the patients suggests that the doses of inhaled corticosteroid used did not differ significantly between the groups. Nedocromil had to be changed for five patients owing to worsening asthmatic symptoms. Four of those who continued on nedocromil for the whole year were from the CG. Only one patient in the IG used nedocromil (dose 8 mg) at 1 yr; four CG patients used a mean dose of 10·5 mg.

Airway responsiveness improved by 0·9 step dose in the IG and 0·7 step dose in the CG, but there was no significant difference between the groups. A normal value >1·6 mg ml^{-1} for provocative doses of histamine was reached by 11 patients (14%) in the IG and by five patients (7%) in the CG.

There was no retirement due to asthma. All use of extra health services was due to problems related to asthma, e.g. worsening of asthma status. The IG had no inpatient days or emergency room visits and recorded 75 sickness days. The CG needed 29 health centre and two emergency room visits, 19 specialist consultations and 16 inpatient days, and recorded 2·5 times more sickness days (190 days) than the IG. However, because of a great variance, there was no significant difference between the groups in any item of extra cost (Table 4).

The average total time required by the intervention was 8 h per patient. The total annual cost was FIM 2757 per patient in the IG, of which FIM 1978 was due to the intervention. In the CG the total cost was FIM 2351 per patient. The difference is statistically significant (P=0·0000) as is the difference in direct costs, whereas the indirect costs were nearly significantly lower in the IG (P=0·067) (Table 5). The total average transportation cost because of intervention was FIM 216 per patient.

All cost-effectiveness ratios are in favour of the intervention regardless of what effectiveness measure is used. The positive incremental ratios show that a unit of possible extra effectiveness comes at a price. For example, a one percentage point improvement in FEV_1 with the intervention costs FIM 86 (Table 6). In terms of purely

TABLE 3. The mean HRQOL scores at baseline and at 1 yr in the intervention and control groups (95% CI in parentheses)

	Intervention group		Control group		Difference between the groups at 1 yr
	At baseline	At 1 yr	At baseline	At 1 yr	*P* values
15D	0·89 (0·87–0·91)	0·93*** (0·90–0·94)	0·89 (0·86–0·91)	0·91*** (0·89– 0·94)	0·47
SGRQ total	26·4 (23·8–30·7)	16·5*** (13·7–20·0)	27·9 (24·6–31·5)	20·5*** (16·4–24·4)	0·16
SGRQ symptom	57·5 (54·1–62·1)	37·8*** (33·4–43·0)	57·8 (53·8–62·8)	40·1*** (34·4– 45·2)	0·66
SGRQ activity	27·8 (23·8–32·9)	18·2*** (14·1–22·4)	28·0 (23·3–33·1)	22·4*** (17·1–27·8)	0·22
SGRQ impact	15·6 (13·1–20·1)	8·7*** (6·3–11·8)	18·2 (14·9–21·4)	13·1*** (9·5– 16·3)	0·08

Significance of the difference between baseline and one year, paired samples *t* test: ***$P<0·001$. HRQOL, health-related quality of life; 15D, the generic HRQOL instrument; SGRQ, the disease-specific St George's Respiratory Questionnaire.

TABLE 4. The mean extra costs per patient in FIM in the intervention and control groups after the first treatment year (range in parentheses)

	Health centre care	Specialist care	Emergency care	Inpatient care	Extra corticosteroids	Extra antibiotics	Indirect costs due to sickness days
Intervention	32 (0–356)	95 (0–1546)	0	0	7 (0–120)	12 (0–220)	623 (0–12 087)
Control	165 (0–890)	21 (0–2319)	30 (0–1200)	24 (0–12 000)	24 (0– 360)	23 (0–44)	1733 (0–63 990)
Difference, *P* values	0·27	0·45	0·79	0·79	0·20	0·47	0·56

FIM, Finnish mark (£1 sterling approx. FIM 8).

monetary cost–benefit, the intervention resulted in a negative net benefit (loss) of FIM 406 per patient.

Discussion

The patients in this study were mild asthmatics (based on the FEV_1 values). Even so, all outcome measures indicated a significant improvement in the IG. At 1 yr the IG showed a better result that the CG in all outcome variables, but statistically the groups differed significantly from each other only in FEV_1. From a clinical point of view that is noteworthy, because it characterizes an improvement in bronchial obstruction.

Nowadays there is a wide consensus over employing an early anti-inflammatory regimen in new asthmatics to avoid chronic severe asthma with a disabling pulmonary obstruction. Our results strengthen that view, stressing the importance of guided self-management education in an early phase to avoid later obstruction. The better FEV_1 in the IG could be a result of better self-management skills due to intervention or effective supervision every third month. It is difficult to estimate how much education alone has contributed to the results.

It is difficult to conduct a randomized trial of educational programmes, because patients randomized to the control group can obtain information about the intervention. Lack of blinding is another methodological problem. To minimize these risks the patients were made aware of the study protocol to the extent that there were to be two groups, but they did not know the details of the programme in advance. The baseline education for self-management was similar for all patients and at that stage the attending chest physician did not know the result of randomization. The patients filled in the HRQOL questionnaires by themselves and the clinical measurements were not carried out by the chest physician who ran the trial. Therefore lack of blinding should not be a major worry.

The difference in the improvement rate of airway hyperreactivity between the groups was not significant. Treatment in usual clinical practice, where the patients themselves were responsible for buying their drugs,

TABLE 5. The mean direct, indirect and total costs per patient in FIM in the intervention and control groups during the first treatment year (range in parentheses)

	Direct costs	Indirect costs	Total costs
Intervention group*	1269 (1123–2669)	1489 (855–12 942)	2757 (1978–14 065)
Control group	595 (0–12 298)	1727 (0–64 038)	2351 (0– 64 627)
P values†	0·0000	0·067	0·0000

*Includes intervention costs: direct FIM 1123; indirect FIM 855.
†Mann–Whitney test.
FIM, Finnish mark (£1 sterling approx. FIM 8). The costs of visits for diagnosis, randomization and 1 yr follow-up and regular drug therapy are not included.

TABLE 6. The cost-effectiveness ratios in FIM in the intervention and control groups and the incremental cost-effectiveness ratios for intervention with different effectiveness measures

	Intervention	Control	Incremental cost-effectiveness ratio for intervention
15D	689	1176	203
SGRQ total	278	318	162
FVC	541	1069	140
FEV_1	417	1237	86
PD_{15} (in dose step)	3169	3617	1845
PEF	373	635	110

decreased airway responsiveness less than reported by Juniper *et al.* in a double-blind randomized study. In it 16 adult mild asthmatics were treated with 0·4 mg budesonide for 1 yr and five patients returned to a normal level of airway responsiveness (25). The patients of this study attained the same improvement rate as the 58 children treated with 0·2 mg budesonide, t.i.d., by Van Essen-Zandvliet *et al.* When evaluated at 8 months, seven patients (12%) were in remission (26).

The disease-specific and generic HRQOL scores improved significantly in both groups, but there was no significant difference between the groups. The clinical importance of these HRQOL changes and their relationship to clinical parameters are not yet known and need to be further explored.

The costs of extra health services in the CG varied from zero to FIM 64 627 with a mean of FIM 2351. These costs per patient in that group were higher than the intervention costs alone. After randomization the CG had the next planned visit in 11 months time, which can partly explain the need for extra health services. The IG, however, had a visit to the clinic every third month. Their cost of extra health services was only 33% of that in the CG, varying from zero to FIM 12 087.

All cost-effectiveness ratios were in favour of the intervention regardless of what effectiveness measure is used in spite of the fact that the total costs were significantly higher in the intervention group. However, since there was no statistically significant difference between the groups in any effectiveness variable except FEV_1 and there was a significant difference in total costs in favour of the conventional programme, it cannot be unambiguously concluded that the intervention was more cost effective than the conventional programme. Rather, the significances suggest the contrary, reducing the cost-effectiveness analysis to a cost-minimization study. However, the fact that at 1 yr the IG showed a consistently better, but not statistically significantly better, result in all outcome variables might be indicative of a true difference, but the sample sizes are too small to substantiate it.

The incremental cost-effectiveness ratios show the extra cost per unit of extra effectiveness that the intervention produces over the conventional programme. The fact that all incremental ratios are positive suggests that a unit of possible extra effectiveness in the intervention programme comes at an extra cost and that the conventional programme dominates the intensive one regardless of the effectiveness measure. The smallest extra cost (FIM 86) occurs when effectiveness was measured by FEV_1. It was also the only effectiveness variable in terms of which the groups differed significantly. Also, a purely monetary cost–benefit calculation showed that the intervention resulted in a negative net benefit (loss) of FIM 406 per patient. However, viewed in another way, at an extra cost of FIM 406 the intervention produced a significant improvement in FEV_1. Whether the difference is clinically so significant that is justifies the extra cost is for the doctors to decide. Actually it is not known what constitutes a clinically relevant improvement in FEV_1 among new mild asthmatics.

FitzGerald (27), Bosley *et al.* (28) and Kolbe *et al.* (29) emphasize that asthma education should be more individualized and better directed because of many behavioural and psychosocial barriers. Therefore it would be important to be able to identify at baseline which patients may not benefit from a conventional education programme, but might benefit from an intensive one. Moreover, a 1 yr follow-up may be too short a period for drawing firm

conclusions about the cost-effectiveness of an intensive education programme for a chronic condition.

In conclusion, in 1 yr follow-up the intensive patient education for the self-management of newly diagnosed mild asthmatics produced a significantly better outcome than the conventional programme only in terms of FEV_1. When effectiveness was measured by HRQOL scores, there was no significant difference between the programmes. The intervention was not superior to the conventional programme in terms of either cost-effectiveness or monetary net benefit. A longer follow-up of mild asthmatics may be needed before definitive conclusions about the cost-effectiveness of this kind of intervention can be drawn.

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